





antiviral therapy for HIV. Figure 1 shows that the CD 4+ T cell concentrations for a group of subjects who received IL-2 is maintained after discontinuation of antiviral therapy, as compared to baseline CD 4+ cell concentrations measured before antiviral therapy was discontinued. Figures 2 and 3 demonstrate that CD 8+ T cell and Natural Killer cell concentrations are elevated in patients receiving IL-2, again as compared to baseline cell concentrations before discontinuation of antiviral therapy. This data demonstrates that immune enhancement, as defined in the specification and recited in claim 19, is achieved when patients are administered IL-2 in accordance with the present invention.

Immune enhancement, as defined in the specification and recited in the claims, is achieved for patients who have discontinued antiviral therapy and have detectable levels of HIV. Comparing the cell concentrations of CD 4+, CD 8+, and Natural Killer Cells in Figures 1-3, and the viral loads shown in Figure 4, it is evident that these cell concentrations are *not* dependent on the HIV viral loads for those patients receiving low-dose IL-2. As set forth in the declaration, the data submitted with the declarations shows that CD 4+, CD 8+, and Natural Killer cell concentrations were not affected by the detectable HIV viral loads shown by patients after discontinuation of antiviral therapy, when these patients are administered low-dose IL-2. While the viral loads of patients receiving IL-2 in the attached declaration were initially below the lower limit of detection upon discontinuation of treatment, the Examiner has not provided any information that refutes the direct showing submitted herewith that immune enhancement, as defined in the claims, is not dependent on HIV viral loads.

Regarding **points 2 and 3 above**, applicant respectfully submits that the attached declaration, along with Example 2 of the specification show that low-dose IL-2 is capable of generating the type of immune response claimed. Figure 1 demonstrates that CD4 + T cell concentrations for the patients administered IL-2 were generally at or above baseline after discontinuation of antiviral therapy. Figure 2 demonstrates that CD8 + T cell concentrations for the IL-2 group were generally above baseline after discontinuation of antiviral therapy. Figure 3 demonstrates that Natural Killer cell concentrations for the IL-2 group were generally above baseline after discontinuation of antiviral therapy.

Regarding **point 5** above, applicant notes that the absence of working examples will not by itself render the invention non-enabled. MPEP § 2164.02 "None or One Working Example". Particularly:

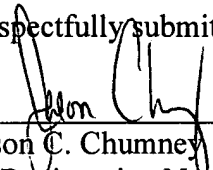
The presence of only one working example should never be the sole reason for rejecting the claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors. Id.

Applicant submits that, upon consideration of all the factors discussed above, including the attached declaration, the claims are enabled and the rejection should be withdrawn.

In view of the above remarks, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

By  \_\_\_\_\_

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Attachments